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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/851,595	05/08/2001	Wei Gu	MNI-080CP	2613

7590 05/29/2003

INTELLECTUAL PROPERTY GROUP
MILLENNIUM PHARMACEUTICALS, INC.
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EXAMINER

MERTZ, PREMA MARIA

ART UNIT PAPER NUMBER

1646

DATE MAILED: 05/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/851,595

Applicant(s)

Wei Gu

Examiner

Prema Mertz

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 1, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-32 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Art Unit: 1646

DETAILED ACTION

1. Claims 1-22 have been canceled in Paper No. 11, 10/11/02. Claims 24-32 and amended claim 23 (Paper No. 13, 4/1/03) are under consideration.
2. Receipt of applicant's arguments and amendments filed in Paper No. 13 (4/1/03) is acknowledged.
3. The following previous rejections and objections are withdrawn in light of applicants amendments filed in Paper No. 13, 4/1/03:
 - (i) the objection to the specification and title of the invention.
4. Applicant's arguments filed in Paper No. 13 (4/1/03), have been fully considered but were persuasive in part. The issues remaining and new issues, are stated below.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 101

6. Claims 23-32 are rejected under 35 U.S.C. § 101.

This rejection is maintained for reasons of record set forth at pages 2-6 of the previous Office action (Paper No. 12, 11/29/02).

Applicants argue that the specification teaches that the claimed polynucleotides are useful in the identification of compounds which modulate LGR6 in an attempt to identify candidate compounds for treatment of LGR6 disorders i.e. weight disorders, cardiovascular or CNS disorders. However, contrary to Applicants assertions, it is clear from the instant specification

Art Unit: 1646

that the instantly claimed nucleic acids encode what is termed an "orphan receptor" in the art. This is a protein receptor whose cDNA has been isolated because of its similarity to known proteins, i.e. the LGR5 mouse protein to which the human LGR6 protein is 65% identical shares similarity to human HG38, rat LGR5 and LGR4 G-protein coupled receptors (see page 114, lines 15-31). The translation product of the LGR6 protein encoded by the claimed nucleic acid, shares sequence homology other putative G-protein coupled receptors (page 114). Until some actual and specific significance can be attributed to the LGR6 protein identified in the specification as having homology to other putative G-protein coupled receptors (page 114), the instant invention is incomplete.

Applicant has traversed this rejection on the premise that a claimed nucleic acids are useful in the identification of compounds which modulate LGR6 in an attempt to identify candidate compounds for treatment of LGR6 related disorders. The employment of a protein encoded by a nucleic acid of the instant invention, in such a method is not a credible, substantial or specific utility. To grant Applicants a patent encompassing an isolated protein of as yet undetermined biological significance would be to grant Applicant a monopoly "the metes and bounds" of which "are not capable of precise delineation". That monopoly "may engross a vast, unknown, and perhaps unknowable area" and "confer power to block off whole areas of scientific development, without compensating benefit to the public" *Brenner v. Manson, Ibid*). To grant Applicant a patent on the claimed nucleic acid encoding a polypeptide based solely upon an assertion that the

Art Unit: 1646

protein has 65% homology to human HG38 receptor, is clearly prohibited by this judicial precedent since the compensation to the public is not commensurate with the monopoly granted.

There has to be physiological significance for the nucleic acid encoding the LGR6 polypeptide disclosed in the specification. This requirement is analogous to basic scientific characterization, however, in the instant case no substantial benefit for the claimed protein is currently disclosed, but an exploratory significance. Furthermore, contrary to Applicants arguments, the employment of the LGR6 polypeptides of the instant invention, in identification of compounds which modulate LGR6, is not a substantial or specific utility.

In the absence of any disclosed relationship between the claimed nucleic acid encoding LGR6 protein and any disease or disorder and the lack of any correlation between the protein with any known disease or disorder, any information obtained from an expression profile on page 27 and pages 86-93 would only serve as the basis for further research on the observation itself. "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing." *Brenner*, 148 USPQ at 696. The disclosure does not present a substantial utility that would support the requirement of 35 U.S.C. §101.

In conclusion, Applicants arguments with respect to utility of the instant nucleic acid encoding an LGR6 polypeptide, are found to be non-persuasive. Contrary to Applicants arguments, the instant specification does not disclose a single credible, specific or substantial

Art Unit: 1646

utility for the instant nucleic acid encoding LGR6 polypeptide. The initial burden to demonstrate or present such is on Applicants.

Claims 23-32 also remain rejected under 35 U.S.C. 112, first paragraph, as failing to adequately teach how to use the instant invention. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim rejections-35 USC § 112, first paragraph

7. Claims 23-32 are rejected under 35 U.S.C. § 112, first paragraph.

This rejection is maintained for reasons of record set forth at pages 6-10 of the previous Office action (Paper No. 12, 11/29/02).

Applicants state that this rejection is traversed but have not submitted arguments demonstrating the error in this rejection by the Examiner and therefore this rejection is being maintained for reasons of record.

Claim rejections-35 USC § 112, second paragraph

8. Claims 23-32 are rejected under 35 U.S.C. § 112, first paragraph.

Claim 23 recites the limitation "LGR6 activity". However, it is unclear what this activity is. The metes and bounds of the activity are unclear.

Conclusion

No claim is allowable.

Art Unit: 1646

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP.. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 305-3014 or (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 746-5300.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the

Art Unit: 1646

Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Prema Mertz
Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646
May 9, 2003